# Drug Use Investigation for Arzerra Chronic Lymphocytic Leukemia (CLL) (116789)

**First published:** 26/06/2015

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS10093

**Study ID**

48996

**DARWIN EU® study**

No

**Study countries**

☐ Japan

**Study description**

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

### Multiple centres: 150 centres are involved in the study

## Contact details

**Study institution contact**

Clinical Disclosure Officer Clinical Disclosure Officer
trialandresults.registries@novartis.com

**Study contact**

trialandresults.registries@novartis.com

**Primary lead investigator**

Clinical Disclosure Officer Clinical Disclosure Officer

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned: 31/12/2012

Actual: 25/12/2012

---

**Study start date**
Planned: 31/07/2013

Actual: 30/07/2013

---

**Data analysis start date**
Planned: 30/06/2022

Actual: 05/04/2022

---

**Date of final study report**
Planned: 15/11/2022

Actual: 14/06/2022

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Novartis

# Study protocol

gsk-116789-protocol-redact.pdf(109.66 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

Non-EU RMP only

# Other study registration identification numbers and links

COMB157A1401

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

---

**Main study objective:**

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Multicenter observational study

## Study drug and medical condition

**Name of medicine**

ARZERRA

---

**Medical condition to be studied**

Chronic lymphocytic leukaemia

## Population studied

**Short description of the study population**

The study involved a multicenter observational investigation of Arzerra, a drug used to treat relapsed or refractory chronic lymphocytic leukemia. The target sample size was 300 patients, and data was obtained after administration under actual use conditions. A central registration system was adopted for patient enrollment.

Patients who received Arzerra for the indication of relapsed or refractory CD20-positive chronic lymphocytic leukemia were included in the study. Patients who started receiving Arzerra before the study contract concluded were also considered study patients.

---

**Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

---

**Special population of interest**

Hepatic impaired

Immunocompromised

Other

Pregnant women

Renal impaired

---

**Special population of interest, other**

Patients with chronic lymphocytic leukemia

---

**Estimated number of subjects**

300

## Study design details

**Outcomes**

Information regarding the safety and efficacy of Arzerra under the actual post-marketing use conditions of the product.

**Data analysis plan**

Items related to patient disposition, patient demographic and baseline characteristics, items related to safety, and items related to efficacy

## Documents

**Study results**

ReExam-COMB157A1401-CSR-E_Redacted.pdf(1.57 MB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No